REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1, 9-10, 19-20, 22-23, 25 and 31-32 have been amended. Claims 2, 13, 21, 24 and 28-30 have been canceled. Support for the amended claims may be found at page 7, lines 6 to 18 and page 9, lines 2 to 24. The amendments are being made solely to advance prosecution of this application to allowance and do not constitute an acquiescence, abandonment or disclaimer with respect to any subject matter originally claimed. Applicants reserve the right to pursue any excluded subject matter by way of one or more further application(s).

Specification

The Examiner has objected to the disclosure because of a number of informalities. The informalities arising from typographical errors have been corrected. However, it is not necessary to correct words that have multiple acceptable spellings.

Drawings

The Examiner has objected to Figure 2 because "Fluorecence" should be "Fluorescence". This error has been corrected on attached replacement drawing sheet 2/3.

Claim Objections

The Examiner has objected to claim 22 because in line 2 "Kostmann morbus" should be "morbus Kostmann" for consistency with the rest of the application. An appropriate correction has been made.

Claim Rejections – 35 U.S.C. §112

The Examiner has rejected claims 1-8, 10-12 and 20-27 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse the rejection.

The Examiner considers that it is unclear how one determines if any particular level is not normal if there are no control levels determined and compared to. In addition, the Examiner

considers that the metes and bounds of what constitutes a "low level" are unclear because the specification merely gives examples, and does not define the term.

Independent claims 1, 10, 20, 23 and 25 have been amended to delete the term "optionally" and to specify that the control sample is "from a normal subject". These claims have also been amended to replace to the phrase "low level of LL-37" with the expression "lowered level of LL-37 compared to the level of LL-37 in said control sample".

Accordingly, the claims now require the level of LL-37 to be compared to a defined control example. Therefore, it is clear how one determines if any particular level is not normal. In addition, the metes and bounds of what constitutes a "lowered level of LL-37 compared to the level of LL-37 in said control sample" are clear.

Withdrawal of the objection made under the second paragraph of 35 U.S.C. §112 is respectfully requested because the amended claims are clear and definite.

The Examiner has rejected claims 9, 14, 19 and 29-31 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for methods for the determination of levels of LL-37 in body fluids and *in vitro* methods for bactericidal assays utilizing LL-37, allegedly does not reasonably provide enablement or compositions for methods of treatment *in vivo*. Applicants respectfully traverse the rejection.

Independent claims 9, 19 and 31 have been amended to specify that the subject being treated has a lowered level of LL-37 compared to a normal subject. Thus, claims 9 and 14-19 are drawn to a method of treating an individual to reduce the risk of infection comprising administration of an amount of LL-37, wherein the individual has a lowered level of LL-37 compared to a normal subject. Claim 31 is drawn to a method of treating an infection in a subject by administration of a therapeutically active amount of LL-37, wherein the subject has a lowered level of LL-37 compared to the level of LL–37 in a normal subject.

The prior art teaches that LL-37 is an antimicrobial peptide found in human neutrophils and expressed in skin and gingiva and appears to play an important role in defense against invading pathogens (Weinberg *et al.*). At the time of filing the instant application, it was not known in the art that specific conditions exist in which no LL-37 or lowered levels of LL-37 compared to the level of LL-37 in a normal subject. That such conditions exist was also not predicable from the prior art.

The specification teaches methods for the determination of levels of LL-37 in body fluids and *in vitro* methods for bactericidal assays utilizing LL-37. The specification also teaches that there exist conditions in which individuals have lowered levels of LL-37 and that this lowered level of LL-37 increases the susceptibility of the individual to infection. The instant specification teaches that LL-37 may be administered to these patients to compensate for the lack of naturally expressed LL-37 in order to treat or prevent infection in those individuals.

Thus, the treatment scope of the instant claims is limited to the treatment of individuals who have a lowered level of LL-37 compared to a normal subject. Based on the teaching of the specification, there is a reasonable expectation that such patients may be treated by administering LL-37 to compensate for the lack of naturally expressed LL-37. Furthermore, methods of administration and doses are given in the specification at page 19, line 30 to page 22, line 2.

Withdrawal of the rejection made under the first paragraph of 35 U.S.C. §112 is respectfully requested because the specification enables a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims.

Information Disclosure Statement

An Information Disclosure Statement (IDS) was filed on April 7, 2005. The Examiner crossed out references AM, AO, AP, presumably because the translation check box indicated "no". However, submission of these references was in compliance with the requirements under 37 C.F.R. §1.98(a)(3) because these references were cited in a Search Report and a copy of the Search Report was provided with the IDS that was filed on April 7, 2005. Reconsideration and entry of these references into the record are respectfully requested.

CONCLUSION

Having fully responded to all the pending objections and rejections contained in the Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early notice to that effect. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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